

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: *HÖGBERG, et al.*)
)
Serial No. *To be assigned*)
)
Filed: *Herewith*)
)
Title of Invention:)
)
Method and Apparatus for)
Processing Blood and)
Blood Components)
)
)
_____)

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I, <u>Yanmin Huang</u> , do hereby certify that the foregoing documents are being deposited with the United States Postal Service as Express Mail, postage prepaid, in an envelope addressed to the U.S. Patent and Trademark Office, Box Patent Application, P.O. Box 2327, Arlington, VA 22202, on this date of November 30, 2001	
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PRELIMINARY AMENDMENT

Sir,

Please enter the following Preliminary Amendment for the above-identified Application, filed simultaneously herewith:

IN THE SPECIFICATION:

On page 1, as the first sentence after the title, please insert the following:

This application claims the benefit of International PCT Application No. PCT/SE00/01077 filed 26 May 2000, which claims priority from Swedish Patent Application No. 9903841-6 filed 26 October 1999.

IN THE CLAIMS:

Kindly replace claims 1 – 10 with the following:

1. A method for processing a blood concentrate product for separating a medicinally valuable blood component comprising: connecting at least one product bag containing a blood concentrate product to be processed with a tube system having a plurality of tubes connected to a multi-way connector and connecting also a solution bag containing a diluting solution via a solution tube to the tube system in communication with the multi-way connector, suspending the at least one product bag containing the blood concentrate product to be processed in a cassette, processing the blood concentrate product in the at least one product bag by oscillating the cassette forwards and backwards in an incomplete pendulum swing, adding the diluting solution from the solution bag through the tube system in an adapted portion to each of the at least one product bags, keeping the cassette in motion until all blood concentrate products are dissolved in the added diluting solution, and transferring the contents of all of the at least one product bags in the cassette to a ring bag for a subsequent centrifugation processing step.
2. A method in accordance with Claim 1 whereby the amount of diluting solution added to the at least one product bag may be controlled by a clamp valve through which the solution tube is adapted to be passed and which clamp valve can also be utilised when processing is finalised to weld the solution tube.
3. A method in accordance with Claim 1 whereby the pendulum movement of the cassette is held within approximately a quarter revolution in either the forward or backward direction.
4. A method in accordance with Claim 1 whereby the step of transferring to the ring bag the contents of all of the at least one product bags containing a blood concentrate product occurs after the steps of adding and processing with the diluting solution.
5. A method in accordance with Claim 1 in which the step of adding the diluting solution and the step of transferring the dissolved concentrate products takes place in several steps with mixing as the middle step.

6. A device for processing a blood concentrate product comprising a centrifuge machine to which is connected a cassette in which a plurality of product bags containing blood concentrate products to be processed may be suspended and whereby the cassette can be put in motion in a forward and backward pendulum movement in an incomplete revolution about the axis.
7. A device in accordance with Claim 6 in which the centrifuge machine further has attached thereto an instrument for holding a bag containing a diluting solution.
8. A device in accordance with Claim 6 whereby the pendulum movement of the cassette is maintained within the interval of approximately a quarter revolution forward and backward.
9. A bag set for processing blood concentrate products comprising a ring bag, a processed component bag connected to the ring bag, one or more connecting tubes that are adapted to be individually connected to one or more discrete sources of blood concentrate products, said one or more connecting tubes also being connected to a multi-way connector and a diluting solution tube via the multi-way connector, the diluting solution tube being adapted to be connected to a discrete source of diluting solution, whereby the one or more connecting tubes and the diluting solution tube and the ring bag are connected to the multi-way connector where they can be connected with each other in fluid communication, while the processed component bag is separately connected to the ring bag.
10. A device for processing a blood concentrate product in accordance with Claim 6 further having an outer lid which has a motor disposed therein which operates in an incomplete revolution in one direction immediately followed by a corresponding incomplete return revolution in the other direction, said motor being operably connected to the cassette such that when the outer lid of the centrifuge is in an open position, a plurality of product bags can be suspended in the cassette, so that when the motor is activated the product bags are exposed to a mechanical mixing of the blood concentrate products disposed therein.

Attached hereto is a version of these claims 1 – 10 showing the marked-up changes.

Kindly also add the following claims 11 – 20:

11. A device for processing a blood concentrate product in accordance with Claim 10, which further comprises a clamp valve through which a diluting solution tube may be passed whereby the diluting solution tube is connected between a diluting solution bag and the plurality of blood product bags, and whereby an amount of diluting solution may be added to the plurality of product bags, this amount of diluting solution being controlled by the clamp valve.

12. A device for processing a blood concentrate product in accordance with Claim 11, whereby the clamp valve can also be utilised when processing is finalised to weld the diluting solution tube.

13. A device for processing a blood concentrate product in accordance with Claim 11, which further comprises a support which has a controllable clamp and a welding station which can be actuated to block or weld a diluting solution tube adapted to be disposed therein.

14. A device for processing a blood concentrate product in accordance with Claim 11, which further comprises a second clamp valve to control the flow of processed blood concentrate product from the plurality of product bags to a ring bag via a tube connecting the product bags to the ring bag.

15. A method in accordance with Claim 1, in which the steps of oscillating the cassette and adding diluting solution occur at least partially at the same time.

16. A method in accordance with Claim 1, whereby the connecting step comprises connecting a plurality of blood product bags each containing a blood concentrate product to be processed; and whereby said step of adding a diluting solution includes adding diluting solution to each of the plurality of product bags.

17. A method in accordance with Claim 16 whereby said step of adding a diluting solution includes flowing the diluting solution to each of the plurality of product bags through the multi-way connector.

18. A method in accordance with Claim 16, whereby the step of transferring includes transferring the contents of each of the plurality of product bags to the ring bag.

19. A method in accordance with Claim 18 whereby said step of transferring includes flowing the contents of each of the plurality of product bags to the ring bag through the multi-way connector.

20. A method in accordance with Claim 1 which further comprises a step for removing a processed blood component from the ring bag after the subsequent centrifugation processing step.

* * *

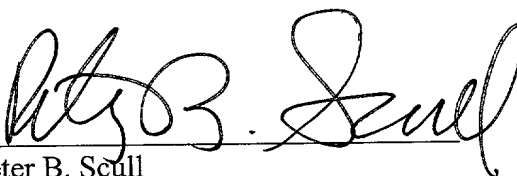
REMARKS

It is believed that this Amendment places the application in better condition for examination and therefore its entry is appropriate.

If prosecution can be expedited in any fashion by telephone conference, the Examiner is urged to call the undersigned at the below-printed telephone number.

Respectfully submitted,

November 30, 2001
Dated


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VERSION SHOWING MARKED-UP CHANGES

1. A method for ~~The way of pre-processing a blood concentrate products from a previous~~
~~centrifuging of whole blood before these concentrate products are exposed to yet another~~
~~centrifuging~~ for separating the recoverable, still accessible, a medically valuable blood
components, **characterised** by comprising: connecting the number of at least one product bags-
(37-40) with containing a blood concentrate products that are intended to be processed included
in the current new centrifuging, along with the respective bag and outlet a tube system having a
plurality of tubes (25-28) connected to a multi-way connector (29) to which and connecting also
a solution bag (23) with containing a diluting solution is joined to supply via a solution tube (30)-
is connected to the tube system in communication with the multi-way connector, after which
suspending the at least one product bags (37-40) with containing the blood concentrate products-
are suspended to be processed in a cassette, (41) which, via the adapted motor, can operate
processing the blood concentrate product in the at least one product bag by oscillating the
cassette forwards and backwards in an incomplete pendulum swing, (42) while adding the
diluting fluid solution from the solution bag through the tube system in an adapted portions is-
added to each of the at least one product bags, with the blood concentrate products from bag (23)-
with diluting solution and whereby keeping the cassette (41) is kept in motion by the motor until
all blood concentrate products are dissolved in the added diluting solution, after which and
transferring the contents of all of the at least one product bags in the cassette are added to a new
ring bag (22) for the a subsequent centrifugation processing step.

2. A mMethod in accordance with Claim 1 ~~characterised in which~~ whereby the amount of
diluting solution added to ~~each respective~~ the at least one product bag is may be controlled by a
clamp valve (11) through which the supply solution tube (30), for the diluting solution, is
adapted to be passed and which clamp valve (11) can also be utilised ~~for~~ when processing is
finalised to weld the solution tube.

3. ~~A mMethod~~ in accordance with Claim 1 ~~or 2 characterised in which~~ whereby the pendulum movement of the cassette (41) is held within ~~+/- approximately~~: a quarter revolution in either the forward or backward direction.

4. ~~A mMethod~~ in accordance with ~~either of Claims 1-3 eharacterised in which~~ whereby the step of transferring to the ring bag the contents in of all of the at least one product bags with containing a blood concentrate products (37-40) occurs after the steps of addingtion of and processing with the diluting solution via a joint multi-way valve (29) to which the tubes are connected then transferred to ring bag (22) in which the consequent centrifuging is carried out.

5. ~~A mMethod~~ in accordance with ~~either of Claims 1-4 that is characterised by the~~ in which the step of adding addition of the diluting solution and the step of transferringence of the dissolved concentrate products takes place in several steps with mixing as the middle step.

6. ~~A dDevice~~ for processing a blood concentrate product comprising a centrifuge machine to which is connected a carrying out the method in accordance with either of Claims 1-5 that is characterised by cassette (41) in which a number plurality of standard product bags (37-40) with containing blood concentrate products from a previous centrifuging can to be processed may be suspended and also via multi-way valve (29) can be connected to source (23) for the controlled addition of diluting fluid and whereby the cassette (41) can be put in motion by a motor in a forward and backward pendulum movement (42) consisting only of in an incomplete revolution about the axis.

7. ~~A dDevice~~ in accordance with Claim 6 ~~that is characterised by also containing an~~ in which the centrifuge machine further has attached thereto an instrument for introducing a holder or holding a bag with containing a diluting solution, which via a control valve is connected to the same multi-way control valve as the bags with blood concentrate products.

8. ~~A dDevice~~ in accordance with Claim 6 ~~or 7 that is characterised thereof by~~ whereby the pendulum movement of the motor being cassette is maintained within the interval +/- of approximately a quarter revolution forward and backward.

9. A bag set for processing blood concentrate products with the method as per either Claim 1-4 and/or device in accordance with either of Claims 6-8 that is characterised thereof by containing comprising a ring bag (22), a processed component bag connected to the ring bag, (23) with diluting solution, one or more than two connecting tubes (25-28) that are intended adapted to be individually connected to a bag with one or more discrete sources of blood concentrate products, said one or more connecting tubes also being connected and to a multi-way connector (29) and a diluting solution tube via the multi-way connector, the diluting solution tube being adapted to be connected to a discrete source of diluting solution, whereby the aforementioned one or more connecting tubes and bag (23) with the diluting solution tube and the ring bag (22) all are connected to the multi-way connector where they can be connected with each other in fluid communication, while a final storage the processed component bag (33) is separately connected to the ring bag.

10. A device Centrifuge (34) for carrying out the method for processing a blood concentrate product in accordance with either of Claims 1-5 is characterised thereby its 6 further having an outer lid (35) which has a motor disposed therein with the special function for activating which operates in an incomplete revolution (42) in one direction immediately followed by a corresponding incomplete return revolution in the other direction, said motor being operably connected to the to and past the point of departure and that this function can be combined with a holder or cassette (41) and such that when the centrifuge's outer lid (35) of the centrifuge is fully in an open position, a number plurality of product bags (37-40) can be suspended in the cassette, so that for when the motor is activated they the product bags are exposed to a mechanical mixing of the existing substance inside blood concentrate products disposed therein.